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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,322	06/14/2001	Frank Robert Busch	PC10734A US	7157

7590 12/13/2004

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/881,322	BUSCH ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-17 and 30* is/are pending in the application.

4a) Of the above claim(s) *8,9 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,10,14-17 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed September 23, 2004 have been entered.

Claims 6-17 and 30 are pending.

Claims 8, 9, and 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-7, 10, 14-17, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpino'369 (WO97/24369 from the IDS filed July 10, 2002) and Carpino'306 (US Patent 6,107,306) in view of Hahn (Chapter 284: "Systemic Lupus

Erythematosus" in Harrison's Principles of Internal Medicine, 13th ed., 1994, page 1643-1648), references of record in the previous office action mailed October 16, 2003.

Carpino'369 teaches the elected compound, compound of claim 10, as the preferred growth hormone secretagogues (See the abstract and claim 90). Carpino'369 also teaches the compound can be orally administered (See page 31, line 10). Carpino'369 also teaches the compound is known to be useful to improve muscle strength and mobility as well as renal homeostasis (See page 31, line 3-4). Carpino'369 teaches the elected compound can be used with other GHS, such as GHR-6, and hexarelin, together in treating the disorders (See particularly the abstract).

Carpino'306 also teaches the same genus of compounds as Carpino'369 and those compounds are useful in treating, in addition to the above mentioned conditions, osteoporosis, improving bone remodeling, promoting cartilage formation, and treating peripheral neuropathy (See col. 27, line 16 – 21).

The references do not expressly teach the elected compound be useful in treating systemic lupus erythematosus (SLE). The references do not teach the employment of a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE.

Hahn teaches the clinical manifestation of SLE can be varied such as arthralgias, necrosis of bone, bone deformities, and peripheral neuropathy (See page 1645, Table 284-2). Hahn also teaches the antimalarial agent, quinacrine, and glucocordicoids such as prednisone, methylprednisolone, and prednisolone are useful in treating SLE (See page 1647, col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected compound to treat SLE. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE.

One of ordinary skill in the art would have been motivated to employ the elected compound to treat SLE because the elected compound is useful to treat the clinical manifestation of SLE such as peripheral neuropathy and renal involvement. One of ordinary skill in the art would have been motivated to employ a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE because antimalarial agent such as quinacrine and glucocorticoids such as prednisone methylprednisolone, and prednisolone are known to be useful to treat SLE. Combining and employing two or more agents which are known to be useful to treat SLE individually into a single composition and method useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Response to Arguments

Applicant's arguments filed September 23, 2004 averring treating the manifestation of SLE not being equal as treating SLE have been considered, but are not found persuasive. The examiner interprets the claims in the broadest reasonable manner. Treating the collateral damage by a disorder would be considered as one of the modalities to treat the very same disorder. Applicant further argues by citing the

example of using antifungal agents to treat AIDS that treating the manifestation of SLE using growth hormone secretagogue (GHS) as not appropriate. Examiner admits that if the treatment of AIDS employing only antifungal agents, then it would not be appropriate. However, employing antifungal, along with other agents, to prevent the opportunistic fungal infection in AIDS patients would be considered as an appropriate treatment for AIDS. Examiner notes that the claims herein recite the transitional phrase, comprising, which is an open-end phrase that the instant invention does not exclude any agents in the method of treating SLE. Furthermore, Merck Manual clearly teaches that treating the manifestation of SLE, e.g., pain, is considered as treating SLE. Therefore, treating the bone involvement, renal involvement, and neuropathy caused by SLE by employing GHS, along with other agents, would be seen as appropriate and effective, absent evidence to the contrary.

Applicant's arguments filed September 23, 2004 averring the cited prior art's failure to teach the mechanism of peripheral neuropathy caused by SLE as the same of other peripheral neuropathy have been considered, but are not considered persuasive. Since the cited prior arts teaches the elected GHS as effective in treating peripheral neuropathy, regardless of the etiology. Absent evidence to the contrary, possessing the teachings of the cited prior arts, one of ordinary skill in the art would have been reasonably expected to employ the elected GHS to treat peripheral neuropathy and SLE thereby.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617